REMARKS

The Office Action dated May 18, 2006, has been carefully reviewed and the following comments are made in response thereto. In view of the following remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Claims 1 to 30 are currently pending in this application. Claims 1 to 24, 27, 29 and 30 are withdrawn under 37 C.F.R. 1.142(b) as being drawn to non-elected inventions. Applicants have amended claims 25, 26, and 28.

Applicants have amended the specification to reflect the most current priority status. Applicants have amended claims 25, 26 and 28 to recite (1) that the substance inhibits the binding between the ligand SDF-1 and the receptor CXCR4, and (2) that the substance selected from i) an anti-CXCR4 antibody, or a fragment thereof possessing binding activity to CXCR4; and ii) an anti-SDF-1 antibody, or a fragment thereof possessing binding activity to SDF-1. Exemplary support for these amendments is found on page 18, lines 9 to 11 and page 17, lines 13 to 15 of the specification. No new matter has been added by these amendments.

Objection to the Specification

The Office Action objected to the specification for failing to reflect the most current priority status. Applicants have amended the specification to reflect the current priority status; therefore, Applicants request withdrawal of the objection.

Objection to the Claims

The Office Action objected to claims 25, 26, and 28 for informalities. Claims 25 and 26 were objected to for use of the phrase "a substance that inhibits the action due to CXCR4." Claim 28 was objected to for use of the phrase "a substance that inhibits the action of CXCR4." Without acquiescing to the merits of the objection and for the sole purpose of advancing prosecution, Applicants have amended claims 25, 26, and 28 rendering the objection moot.

The Rejection under 35 U.S.C. 112, first paragraph should be withdrawn

The Office Action rejected claims 25, 26 and 28 under 35 U.S.C. 112, first paragraph for failing to comply with the written description requirement. The Office Action alleges that the claims contain

subject matter that was not described in such a way as to reasonably convey to one of skill in the art that the inventors at the time of filing of the application had possession of the claimed invention.

As the Examiner is aware, the written description requirement merely requires that the description clearly allow persons of ordinary skill in the art recognize what is claimed (*see* M.P.E.P. 2163.02). The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species. Furthermore, to satisfy the written description requirement, the patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonable conclude that the inventor had possession of the claimed invention (M.P.E.P. 2162).

As amended claims 25, 26, and 28 satisfy the written description requirement. The specification discloses use of the CXCR4 inhibitor for treatment of solid tumor cancer, treatment of neovascularization and suppression of vascularization (*see e.g.* Specification, page 38, lines 15 to 20). The specification also discloses that examples of such agents are an anti-CXCR-4 antibody and fragments possessing the same binding activity (*see* Specification, page 18, lines 9 to 11) and an anti-SDF-1 antibody and fragments possessing the same binding activity (*see* Specification, page 17, lines 13 to 15). Since each and every element of claims 25, 26 and 28 is clearly disclosed in the specification, a person of skill in the art would recognize what is claimed. Therefore, Applicants respectfully request withdrawal of the rejection of claims 25, 26, and 28 under 35 U.S.C. 112, first paragraph.

The Rejection under 35 U.S.C. 102(b) should be withdrawn

Claims 25, 26 and 28 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,563,048 to Honjo *et al.*

As amended claim 25, 26 and 28 are directed to methods of treatment of a disease by administration of a CXCR4 inhibitor, which inhibits the binding between the ligand SDF-1 and the receptor CXCR4. The CXCR 4 inhibitor is either i) an anti-CXCR4 antibody, or a fragment thereof possessing binding activity to CXCR4; or ii) an anti-SDF-1 antibody, or a fragment thereof possessing binding activity to SDF-1. Claim 25 is directed to treatment of a solid cancer, claim 26 is directed to treatment of a disease pathologically caused by neovascularization, and claim 28 is directed to suppression of vascularization.

Honjo *et al.* disclose SDF-1 and DNAs encoding the same. Honjo *et al.* further disclose mono- and polyclonal antibodies against SDF-1 (*see* col. 2, lines 54 to 63). Honjo *et al.* also disclose a

pharmaceutical composition containing such an antibody (*see* col. 2, lines 66 to 68). Honjo *et al.* further disclose that polypeptides of the invention *may* be used for treatment of a specified list of disease (*see* col. 5, lines 18 to 32). This list of diseases does not include solid cancer, a disease pathologically caused by neovascularization, or suppression of vascularization. Honjo *et al.* also disclose that the anti-SDF-1 antibodies can be used "in the determination of the amount of said polypeptide" and "for the purpose of diagnosis of diseases" (*see* col. 5, lines 37 to 45). Honjo *et al.* do not disclose or suggest methods of using anti-SDF-1 antibodies in the treatment of a disease. More specifically, Honjo *et al.* do not disclose methods of treatment of solid cancer, neovascularization, or suppression of vascularization (*see also* page 10 of the Office Action). Furthermore, Honjo *et al.* do not disclose or suggest use of antibodies against CXCR4.

As the Examiner is aware anticipation requires that a prior art reference disclose each and every element of a claim. *Rockwell Int'l Corp. v. United States*, 147 F.3d 1358, 1363 (Fed. Cir. 1998). A reference may anticipate even where the relevant properties of the thing disclosed were not appreciated at the time, *i.e.*, where the properties are inherent. *See Titanium Metals Corp v. Banner*, 778 F.3d 775 (Fed. Cir. 1985). Thus, new uses of old products are not patentable. *See In re Brenner* 494 F.2d 1399, 1403 (CCPA 1974). However, new uses of known processes may be patentable. *See Bristol-Myers Squibb Co. v. Ben. Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001). When a prior art reference fails to disclose each and every element of a claim, that reference cannot anticipate the claim. Anticipation also requires an enabling disclosure. *See e.g. Schering Corp. v. Geneva Pharms.*, Inc., 339 F.3d 1373 (Fed. Cir. 2003).

Honjo *et al.* do not disclose each and every element of claims 25, 26, and 28 and therefore the reference does not anticipate these claims. For instance, Honjo *et al.* do not disclose use of an antibody against CXCR4 or use of such antibodies to suppress vascularization, to treat cancer or treat diseases pathologically caused by neovascularization.

As discussed, Honjo *et al.* do not disclose use of anti-SDF-1 antibodies in the treatment of disease. Honjo *et al.* separately disclose polypeptides derived from human SDF-1 and antibodies disclosed against these polypeptides. The use of the antibodies is only for "the determination of the amount of said polypeptide" and "for the purpose of diagnosis of diseases" (*see* col. 5, lines 37 to 45). Throughout the reference draws a clear distinction between polypeptides and "polyclonal or monoclonal antibodies against the polypeptide of the present invention" (*see* col. 5, lines 37 to 45). As such, definition of polypeptides does not encompass the antibodies. Thus, Honjo *et al.* only disclose that

polypeptides derived from human SDF-1, but not antibodies, may be used to treat diseases such as *e.g.*, inflammatory arthritis (*see* col. 5, lines 19 to 31).

Honjo *et al.* also fail to disclose treatment of solid cancer, treatment of a disease pathologically caused by neovascularization, or suppression of vascularization by use of peptides derived from human SDF-1, or antibodies against SDF-1 or against CRXR4. Solid cancer, a disease pathologically caused by neovascularization, or suppression of vascularization are not one of the specifically enumerated diseases against which polypeptides derived from human SDF-1 are thought to be effective in the Honjo *et al.* disclosure (*see* col. 5, lines 19 to 31). Therefore, Honjo *et al.* do not disclose or teach a concrete application of SDF-1 as well as anti-SDF-1 antibodies for cancer therapy.

Honjo *et al.* do not disclose administration of an anti-SDF-1 antibody. The reference only discloses that anti-SDF-1 antibodies can be used to quantify the amount of SDF-1 in an organism or for the purpose of diagnosing disease but not how. Absent any teaching to the contrary, one of skill in the art would understand this reference to disclose laboratory tests on sample materials but not in a patient. While the reference mentions "pharmaceutical compositions containing a polypeptide of the invention or an antibody thereof, in association with a pharmaceutically acceptable diluent and/or carrier" (col. 2, lines 64 to 66), Honjo *et al.* do not disclose or suggest administration of an anti-SDF-1 antibody (*see* "Application as Pharmaceuticals," col. 5, line 58 to col. 7, line 5).

Even assuming that Honjo *et al.* were to disclose administration of an anti-SDF-1 antibody, Honjo *et al.* do not disclose administration of an anti-SDF-1 antibody for treatment of solid cancer, treatment of a disease pathologically caused by neovascularization, or for suppression of vascularization. In other words, Honjo *et al.* disclose different methods of using an anti-SDF-1 antibody for different purposes. It is established case law that "[n]ewly discovered results of knowing processes directed to the *same* purpose are not patentable because such results are inherent." *Bristol-Meyers Squibb, Inc. v. Ben Venue Labs., Co.*, 246 F.3d at 1376. However, new uses of known processes are patentable. *Bristol-Meyers Squibb, Inc. v. Ben Venue Labs., Co.*, 246 F.3d at 1376. Applicants have not claimed the same process for the same purpose; Applicants have claimed new uses for new processes.

Since Honjo *et al.* do not disclose each and every element of claims 25, 26 and 28, the Honjo *et al.* reference does not anticipate claims 25, 26, and 28. In light of the foregoing remarks and amendments, Applicants respectfully request withdrawal of the rejection of claims 25, 26 and 28 under 35 U.S.C. 102(b).

Conclusion

It is respectfully submitted that all claims are now in condition for allowance, early notice of which would be appreciated. Should the Examiner disagree, Applicants respectfully request a telephonic or in-person interview with the undersigned attorney to discuss any remaining issues and to expedite the eventual allowance of the claims.

If there are any additional fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted
Morgan, Lewis & Bockius LLP

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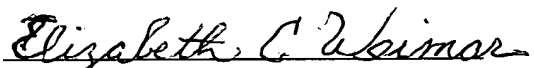
Morgan, Lewis & Bockius LLP
Customer No. **09629**
1111 Pennsylvania Ave., NW
Washington, D.C. 20004
Tel: 202-739-3000
Fax: 202-739-3001



Elizabeth C. Weimar
Registration No. 44,478